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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/689,149

10/20/2003

Miri Seiberg

3282-P02872US04

6375

110 7590 01/20/2010  
DANN, DORFMAN, HERRELL & SKILLMAN  
1601 MARKET STREET  
SUITE 2400  
PHILADELPHIA, PA 19103-2307

EXAMINER

PACKARD, BENJAMIN J

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

01/20/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/689,149	<b>Applicant(s)</b> SEIBERG ET AL.	
	<b>Examiner</b> Benjamin Packard	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 January 1932.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 5-8, 10-12, 14-16, 21-24, 26-28 and 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9, 13, 17-20, 25 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' arguments, filed 10/06/09, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1-4, 9, 13, 17-20, 25, and 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan (US 4,906,457, see IDS filed 07/12/04) in view of Maeda et al (JP 07010772, see IDS filed 07/12/04).

Ryan teaches the administration of a topical composition of protease inhibitors for reducing the risk of skin cancer caused by sunlight or other ultraviolet radiation (col 1 lines 35-40 ) where the composition preferably includes trypsin family of protease inhibitors derived from plants, such as from soybeans (col 1 line 67 spanning col 2 line 2).

Ryan does not specifically teach non-denatured Kunitz-type soybean trypsin inhibitors.

Maeda et al teaches trypsin inhibitors include soybean Kunitz-type trypsin inhibitors, which are rich in the composition disclosed by Maeda et al (English abstract).

Maeda et al does not teach the application of the preparation.

The primary reference specifically teaches the composition preferably includes plant derived trypsin inhibitors, an example of which is disclosed in the secondary reference. As such, one of ordinary skill in the art would find it obvious to use the trypsin inhibitor composition of the secondary reference because it shares this common activity with the composition of the primary reference, and thus would be reasonably predicted to provide corresponding therapeutic effects. See Daichi Sankyo v. Aptotex, 84 USPQ2d 1285 (Fed. Cir. 2007).

**Claims 1-4, 9, 13, 17-20, 25, and 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Joles et al (Br J Radiol, 39 (1966) pp 12-18) in view of Ryan (US 4,906,457, see IDS filed 07/12/04).

Joles et al teaches administration trypsin inhibitors, including soy bean trypsin inhibitors (SBTI, which Applicants assert is Kunitz type in the response filed 03/04/09 pg 10 first paragraph) may be used to reduce the risk of skin damage due to ultraviolet rays (pg 13 and Table II). The trypsin inhibitors are administered via various routes, including oral and topical.

Joles does not specifically teach topical application of the soy bean trypsin inhibitors.

Ryan et al is discussed above for the teaching that soy bean trypsin inhibitors may be applied topically.

It would be obvious to one of ordinary skill in the art apply SBTI of the primary reference using routes known in the art for the same active.

***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-F 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612